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GOAL 3: Safe Food

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GOAL 3: SAFE FOOD

The foods Americans eat will be free from unsafe pesticide residues. Children especially will be protected from the health threats posed by pesticide residues because they are among the most vulnerable groups in our society.

OVERVIEW

Americans enjoy one of the safest, most abundant food supplies in the world due in part to the safe use of pesticides during food production, processing, storage, and transportation. Ensuring the safety of the food supply requires continued diligence by pesticide producers, users, and regulatory bodies. At the Federal level, EPA evaluates the safety of all new and existing pesticides and restricts pesticide use to those applications that do not pose unacceptable human health or ecological risks. The Food Quality Protection Act (FQPA) of 1996 challenged EPA to set new public health standards for pesticides (emphasizing safety for infants and children) and to review approximately 9,700 existing limits on pesticide residues on food over a ten-year period.

Ensuring the protection of children's health by accounting for their special sensitivities and exposures to pesticides remains a priority for the Agency. Unless a different factor is warranted, the Agency applies FQPA's additional ten-fold safety factor in risk assessments to account for children's special vulnerabilities. The Agency also updated pesticide toxicity testing guidelines to better assess risks to infants and children. Outreach activities targeted to address children's susceptibilities continue to provide additional protection by informing parents of potential hazards and steps they can take to minimize or prevent them.

EPA established two objectives in its Strategic Plan to guide its work toward meeting the goal of safe food: reducing risk from use of pesticides and reducing the use on food of pesticides that fail to meet health standards. In FY 1999, EPA progressed toward its long-term objectives by employing a combination of regulatory, outreach, and partnership activities including:

- Continuing the registration and re-registration programs, placing an emphasis on reviewing existing pesticides that pose the greatest health risks while registering lower-risk alternatives.
- Providing outreach, training, and education to pesticide users, applicators, and manufacturers.
- Encouraging the development and adoption of alternative means of pest control, including the use of non-chemical approaches and use of lower-risk pesticides.

FY 1999 PERFORMANCE

Reducing Risk from Agricultural Use of Pesticides

By 2005, EPA's objective is to reduce the risk from agricultural use of pesticides by 50 percent from 1995 levels. To meet this objective, EPA continues to develop and evaluate methods to determine trends in human health and environmental risk posed by pesticides. Unfortunately, the Agency currently lacks methods to measure directly or to estimate reliably these risks on a national or regional basis. Therefore, EPA uses a variety of program activities as surrogate indicators of progress. Although the Agency lacks reliable data on baseline health risks posed by pesticides and on the risks reduced by Agency actions, the overall risk reduction strategy and FY 1999 accomplishments reduced risk in several demonstrable ways.

In FY 1999, EPA committed to decrease adverse risk from agricultural pesticides from 1995 levels and assure that new pesticides that enter the market are safe for humans and the environment through such actions as registering 15 safer pesticide chemicals and biopesticides, issuing 95 new tolerances, and approving 90 new pesticide uses. The Agency exceeded these targets—registering 19 reduced-risk

pesticides (including 13 biopesticides), establishing 351 new pesticide food tolerances, and approving 681 proposed new pesticide uses—while ensuring that all pesticides reviewed met the new health safety standard of "reasonable certainty of no harm" (APG 19). Introducing new reduced-risk chemical pesticides and biopesticides provides food growers with safer pest control alternatives than were previously available. The availability of lower-risk pesticides, combined with public demand for safe food, often leads food growers to switch from higher-toxicity chemicals to reduced-risk alternatives. As the Agency registers new pesticides and ensures that each meets the applicable legal standards, EPA also ensures that pesticide packages have proper labeling and include easily understandable use instructions. These steps contribute to risk reduction by encouraging proper pesticide handling and use.

EPA also took steps in FY 1999 to reduce human health risks from organophosphates, a widely used group of pesticides that can affect human nervous systems. Organophosphates account for over half of all food crop insecticides used in the United States. To address the potential health effects of these pesticides, EPA collaborated with the U.S. Department of Agriculture to form the Tolerance Reassessment Advisory Committee (TRAC). Working through the TRAC, EPA has released for public comment 29 of 40 planned risk assessments for organophosphates, 13 of which were released in FY 1999. Because of the widespread agricultural use of organophosphates, use restrictions, coupled with a lack of safer alternatives for certain uses, could seriously affect some American farmers. Thus, the TRAC has held a number of public technical briefings to communicate risk concerns and obtain the views of stakeholders.

In FY 1999, EPA, working to reduce risks to children through food, also eliminated the use of the organophosphate methyl parathion, one of the most toxic and widely used pesticides, on many crops that contribute to children's diets, including all fruits and many vegetables. The Agency also further restricted the allowable uses of another organophosphate, azinphos methyl, on fruits and eliminated its use on sugar cane. In addition to addressing risks to children, these actions will reduce pesticide risks from worker exposure and agricultural runoff into water bodies.

EXAMPLES OF REDUCING RISK THROUGH REGISTRATION OF REDUCED RISK PESTICIDES

Tebufenozide. This insecticide was registered for use on apples and pears and may serve as an alternative for several organophosphates (OPs). Subsequent to this action, the Agency negotiated the cancellation of methyl parathion for use on these foods, which are common in children's diets.

Bifenthrin. EPA registered new uses for the insecticide bifenthrin for use on many vegetables, including cabbage, certain legumes, eggplant, globe artichoke, canola, and sweet corn. EPA's expedited registration of bifenthrin allowed growers of peas, beans, and sweet corn to begin replacing many OPs for the 1999 crop season. If commercial control is as successful as anticipated, bifenthrin may replace all organophosphate applications on peas, beans, and corn during the year 2000 growing season.

Reducing Applications on Food of Pesticides Not Meeting Health Standards

EPA's objective is that by 2005, use on food of current pesticides that do not meet the new statutory standard of "reasonable certainty of no harm" will be substantially eliminated.

Under FQPA, EPA conducts periodic evaluations of pesticides to assess whether the use of pesticides in accordance with instructions included on their labels presents "reasonable certainty of no harm." Performing this review ensures that all pesticides meet health standards outlined in FQPA. After completing a review and ensuring that the pesticide does not present human or environmental health threats, the Agency issues a Re-registration Eligibility Decision (RED). In cases where the reviews indicate that pesticides do not meet health and environmental requirements, EPA can modify the allowable uses of pesticides, including canceling use or limiting use to certified applicators.

FQPA also created the need for new science policies in a number of areas related to pesticide risk assessment. These include incorporating a ten-fold safety factor for infants and children, considering the risks posed by other pesticides sharing a common toxicity mechanism with the pesticide under review, and considering all non-occupational exposures to the pesticide when setting food tolerances. While the development and updating of science policies do not directly reduce risk from pesticide exposure, these activities enable the Agency to determine whether pesticides meet the FQPA health standards and to select adequate risk reduction measures for those which do not.

In FY 1999, EPA committed, through the re-registration program, to reassess 19 percent of the existing 9,721 tolerances (cumulative 33 percent) for pesticide food uses to meet the new statutory standard of "reasonable certainty of no harm." The total number of tolerances reassessed in FY 1999 was 1,445, or approximately 15 percent of the 9,721 requiring reassessment over the ten-year period from 1996 through 2006. The Agency fell short of achieving its annual performance target due to internal process changes aimed at achieving greater stakeholder involvement in the reassessment process and making the tolerance reassessment process more open to the agricultural community. Although the Agency suffered a slight shortfall in FY 1999, EPA has exceeded the FQPA statutory requirement of evaluating 33 percent of the 9,721 existing pesticide food tolerances, completing a net total of 3,430 reassessments (over 35 percent) (APG 20).

Additionally in FY 1999, the Agency completed 14 REDs. Each RED incorporates risk reduction measures, such as restricting use of products to certified applicators, canceling pesticide products, deleting uses, limiting the amount or the frequency

FIELD, REGIONAL, AND ENFORCEMENT ACTIVITIES SUPPORTING SAFE FOOD

Regions. EPA Regional offices seek to ensure the safety of the nation's food supply by promoting use of reduced-risk pesticides, providing outreach and education to growers and private pesticide users, encouraging the use of alternative pest management strategies, and monitoring post-re-registration use of pesticides. EPA's Regional Agricultural Initiative piloted four projects in the Atlanta, Chicago, San Francisco, and Seattle Regions during FY 1999 with the objective of increasing communication between EPA and stakeholders on FQPA implementation.

EPA Pesticide Laboratories. EPA's pesticide labs provide unique support to food safety functions: setting tolerances, assessing exposure and ecological effects, and performing risk assessments and product chemistry validations. The labs also provide internationally recognized expertise in analyzing dioxin in food. For example, during the recent dioxin food contamination crisis in Belgium, the labs provided technical information and assistance on analyzing for dioxin in contaminated animal feed.

Enforcement Activities. EPA's enforcement program contributes significantly to reduction of agricultural risk:

- Working with the EPA's Regional offices to develop compliance monitoring strategies and conducting compliance assistance and enforcement activities when pesticides are suspended or canceled.
- Developing coordinated outreach/compliance assistance strategies and providing up-to-date information and compliance assistance to the farming community on changes resulting from regulatory actions.
- Addressing referrals from the Food and Drug Administration and/or U.S. Department of Agriculture for over-tolerance residues.

of use, improving use directions and precautions, and employing groundwater or surface water protections. For example, in FY 1999, one RED resulted in the voluntary cancellation of Vernolate for use on peanuts and soybeans, thus eliminating the use on these foods of an acutely toxic pesticide with potentially adverse developmental and neurotoxicological effects.

Other FY 1999 accomplishments include continuation of work with the U.S. Department of Agriculture on the TRAC to obtain broad-based input to the science policies and overall process for the tolerance reassessment program. This input to EPA's pesticide assessment science policies will help ensure the quality and acceptance of the Agency's pesticide risk evaluations and risk mitigation actions. In FY 1999, EPA also published a proposed rule for establishing FQPA Section 18 tolerances that provides guidance on submitting data required to establish tolerances for emergency exemptions. These exemptions allow States and Federal agencies to permit the unregistered use of a pesticide for a limited time if an emergency pest condition exists and no registered, effective pesticide is available.

Research Contributions

Titles III and IV of FQPA identify clear science needs consistent with the evaluation of aggregate exposures to pesticides from multiple sources and cumulative mechanisms of action. The Agency is supporting research to address major uncertainties in assessing the risks from exposure to pesticides and other toxic chemicals, particularly the risks posed to children. Major areas of emphasis and significant accomplishments under the FY 1999 research program include the following:

- Building and evaluating first-generation exposure models that predict total exposure and identify the pathways of exposure (e.g., hand-to-mouth, food, air) with the greatest risk implications for children. The exposure research program completed an initial model, called the Stochastic Human Exposure and Dose Simulation Model for Pesticides (SHEDS-Pesticides) and presented it to the Science Advisory Panel on September 2, 1999. While it is still in an early stage of development, the preliminary results have helped researchers better understand the events and factors that lead to pesticide exposure. As development continues, the model will help identify areas of greatest uncertainty and those needing more research.
- Developing test methods and predictive models to evaluate variability in response to pesticide exposure due to factors such as age, sex, pre-existing disease, health and nutritional status, and genetic predisposition. This health effects research is an ongoing, long-term effort. The program will produce results over the next several years that will apply to several phases of FQPA implementation.
- Collecting and analyzing data on six target pesticides present in urine in individuals aged six and older under the National Health and Nutrition Evaluation Survey (NHANES-IV) and analyzing NHANES-III and earlier data on children. The study design was completed in 1998, and a two year sampling period began in 1999. Data from the study are expected to be available starting in 2001. The conceptual results should be applicable to exposure data on food residues and should enable the Agency to conduct at least preliminary or screening level risk assessments for intermittent, multi-chemical exposures.

PROGRAM EVALUATION

In FY 1999, EPA expanded a process evaluation initiated in 1998 to ensure that regulatory activities meet the FQPA standards. In carrying out the evaluation, the Agency found a need for greater public comment in the development of risk assessments and in risk management decisions. A greater public role in decision-making provides real-world information from a variety of outside parties and assists in informing Agency decisions. To facilitate public participation, EPA instituted a Risk Assessment/Risk Management Pilot for the organophosphate pesticides. EPA chose the organophosphates for this pilot because of their acute and chronic toxicity to humans and wildlife and their widespread application on crops and in residential and commercial settings. Activities facilitated through the pilot included public meetings, technical briefings, and

increased Agency attention to concerns raised by stakeholders. In FY 1999, EPA expanded this pilot by publishing additional preliminary risk assessments and science policy issue papers for public comment, allowing stakeholders to review these documents, provide comments, and contribute to their improvement. Through this pilot, the Agency will evaluate its risk assessment policies, procedures, and processes, providing more inclusive stakeholder participation and ultimately improving EPA's risk assessment process.

CONCLUSIONS AND CHALLENGES

EPA's approach to achieving the long-term strategic goal of ensuring a safe food supply combines regulatory, voluntary, and cooperative risk reduction strategies. While maintaining the high productivity of the registration, re-registration, and tolerance reassessment programs, the Agency also recognizes that program activities alone do not provide an adequate measure of effectiveness in achieving risk reduction. The Agency is continuing to develop more direct measures of risk, without impeding the progress of programs mandated by statute. The Agency's priorities in ensuring safe food remain to address those agricultural pesticides posing the greatest health risks, to encourage lower-risk means of pest control, and to protect vulnerable populations, particularly children, from pesticide risk. The Agency faces major challenges:

- Ensuring the consistency of science policies and regulatory decisions with the latest scientific standards.
- Maintaining a balance between stakeholder participation and meeting statutory deadlines.
- Measuring the effects of regulatory actions in terms of risk prevention or addressing and measuring the effects in terms of risk reduction.
- Funding the re-registration program after FY 2001, when the fees that support it expire.
- Balancing needs for resources between immediate program requirements and the resource-intensive commitment to develop tools to track progress toward outcome-oriented goals.

KEY MILESTONES FOR THE FUTURE

- Complete in FY 2000 the reassessment of all organophosphate pesticides and take appropriate action to reduce agricultural pesticide risk and eliminate those that do not meet current health standards.
- Reassess in FY 2000 the tolerances for atrazine to provide protection for groundwater supplies.
- Finalize in FY 2000 the FQPA science policies to assure that aggregate exposure and cumulative risk are appropriately addressed in pesticide risk assessments.
- Complete by FY 2002 an additional 33 percent of the 9,721 tolerances requiring reassessment.
- Complete by FY 2006 actions on all 9,721 tolerances subject to reassessment under FQPA and all 612 pesticide active ingredient cases subject to re-registration.

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